

## **Non-Opioid Pain Management (Subcommittee of Addiction Action Committee)**

### **Meeting Minutes**

March 27, 2018

4:00 p.m. – 6:00 p.m. EST

Department of Health and Social Services Chapel

Herman M. Holloway Campus

1901 N. Dupont Highway

New Castle, Delaware 19720

#### **Subcommittee Attendees**

Matt Denn, Delaware Department of Justice

Karyl Rattay, Department of Health and Human Services Division of Public Health

Joanna Suder, Delaware Department of Justice

Steve Groff, Department of Health and Human Services Division of Medicaid & Medical Assistance

Lisa Zimmerman, Department of Health and Human Services Division of Medicaid & Medical Assistance

Elizabeth Brown, Department of Health and Human Services Division of Medicaid & Medical Assistance

Richard McKay, Advanced Back & Neck Pain Center

Sandra Gibney, St. Francis

Avani Virani, Highmark

Pam Price, Highmark

Chas Barker, Delaware Physical Therapy Association

David Mangler, Department of State

Mark Bicket, Johns Hopkins Medicine

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#### **I. Welcome and Introduction**

4:02 p.m. – Meeting started. Attorney General Matt Denn provided opening remarks.

#### **II. Discussion of proposed statutory changes to remove any insurance barriers to prescribers recommending and prescribing scientifically tested non-opioid treatments to their patients suffering from back pain.**

4:05 p.m. – Dr. Avani Virani (Medical Director, Health Plan CMO Organization, Highmark) shared Highmark's estimates of the cost impacts resulting from adding the provisions exempting member with a diagnosis of back pain from existing physical therapy and chiropractic visit limits and adding coverage for acupuncture for the same population. Adding yoga and massage, the costs are estimated a little under \$12/year additional cost per member for commercial, Medicaid, and State of Delaware employees. Highmark would need to define eligible providers for Yoga and the cost estimates are only for low back pain. Highmark does not provide coverage for yoga or massage therapy and a majority of the commercial population also does not provide coverage of these services.

4:10 p.m. – Attorney General Denn summarized Highmark's estimates and asked for cost estimates for the State of Delaware's Medicaid program.

4:13 p.m. – Steve Groff (Director, DHSS Division of Medicaid and Medical Assistance) shared estimated costs for Medicaid. The Medicaid numbers are similar to Highmark’s estimates. DMSS estimates \$0.97 annual cost per-member, per-month. The Division of Medicaid and Medical Assistance consulted with the State of Oregon on these numbers. \$600,000 is roughly the estimated state share.

4:16 p.m. – Attorney General Denn led a discussion around Draft Motion #1. It was noted, Senator Stephanie Hansen (D, SD-10) is interested in introducing legislation.

***DRAFT MOTION #1:***

Having reviewed cost estimates prepared by Highmark, the State Employee Benefits Program, and the state’s Medicaid program, the subcommittee recommends that the Addiction Action Committee issue a formal recommendation that the state make statutory changes to remove any insurance barriers to prescribers recommending and prescribing scientifically tested non-opioid treatments to their patients suffering from chronic low back pain. Due to both cost and legal concerns, and given the absence of any other state models to review in order to predict the outcomes of this program with certainty, the subcommittee recommends that this step be taken in stages.

Specifically, the subcommittee recommends that state law be amended so that insurance plans with respect to which the state can mandate coverage be required to provide the following treatments to patients suffering from chronic back pain, in place of opioid drugs:

1. Physical therapy and exercise therapy, with no annual cap on the number of permitted visits. Coverage would not be required for maintenance treatment.
2. Chiropractic therapy, with no annual cap on the number of permitted visits. Coverage would not be required for maintenance treatment.
3. Psychological therapy (which should already be covered under the state’s mental health insurance parity statute).

In subsequent years, the subcommittee recommends that state law be amended so that insurance plans with respect to which the state can mandate coverage be required to provide the following treatments to patients suffering from chronic back pain, in place of opioid drugs:

1. Massage therapy performed by a Delaware Licensed Massage Therapist.
2. Yoga instruction provided by an adequate network of providers meeting the insurer’s quality standards.
3. Acupuncture by a Delaware licensed acupuncture therapist or Delaware licensed acupuncture and eastern medicine practitioner.

We also recommend that the state’s Medicaid program afford the same coverage options to individuals on Medicaid with chronic back pain.

Finally, we recommend that the State Employee Benefit Committee afford this coverage to individuals receiving their health insurance through the state's State Employee Benefit program.

4:23 p.m. – Dr. Karyl Rattay (Director, DHSS Division of Public Health), Dr. Mark Bicket (Assistant Professor, Johns Hopkins University School of Medicine, Department of Anesthesiology and Critical Care Medicine), Dr. Sandra Gibney (St. Francis), Dr. Chaz Barker, and Dr. Virani discussed massage therapy and yoga:

- few and far between number of states have regulated yoga
- Medicaid is not the best place to run small pilots because of the lengthy waiver process
- there are stronger clinical trials when it comes to studying yoga compared to massage therapy
- with yoga there are concerns regarding an instructor's qualifications, experience, licensing, and credentialing.

Dr. Richard McKay (Advanced Back & Neck Pain Center) mentioned the idea of a pilot program. Dr. Rattay thought the Division of Public Health could have a grant and would look into it further.

The subcommittee approved Draft Motion #1 with modifications that will be circulated to committee members for review. The subcommittee voted unanimously.

### **III. Discussion of education of prescribers and patients with respect to risks of opioids and alternatives to opioids**

5:05 p.m. – General discussion around prescribing opioids for acute and chronic pain. Attorney General Denn will amend draft motion to include tapering of opioid use.

### **IV. Discussion of Draft Motion #2**

5:30 p.m. – Subcommittee discussed education requirements and mechanics.

#### ***DRAFT MOTION #2***

The subcommittee believes that proper education of prescribers with respect to the risks of opioid drugs and the effective alternatives to opioid drugs is critical. Therefore, the subcommittee recommends that the state's biennial continuing education requirement for persons holding licenses to dispense controlled substances in Delaware be amended to require state approval of the courses accepted for fulfillment of this requirement, and that the state ensure that approved courses properly discuss the risks of opioid drugs and effective alternatives to opioid drugs.

The subcommittee approved Draft Motion #2 with modifications that will be circulated to committee members for review. The subcommittee voted unanimously.

## **V. Discussion around informed consent.**

5:44 p.m. – A model informed consent form from the National Institute on Drug Abuse was shared with the Subcommittee for review and discussion.

# Sample Informed Consent Form

## Introduction

**This sample informed consent form can be used with patients who are beginning long-term therapy with opioid analgesics to help ensure they understand the side effects, risks, conditions, and purpose of their treatment. This document can help facilitate clear communication between patients and healthcare providers about long-term opioid therapy, clearly define treatment expectations, and resolve any questions or concerns patients may have before treatment initiation.**

## Opioid Therapy for Chronic Pain: Sample Informed Consent\*

*Please review the information listed here and put your initials next to each item when you have reviewed it with your provider and feel you understand and accept what each statement says.*

\_\_\_\_\_ My provider is prescribing opioid pain medications for the following condition(s):

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\_\_\_\_\_ When I take these medications, I may experience certain reactions or side effects that could be dangerous, including sleepiness or sedation, constipation, nausea, itching, allergic reactions, problems with thinking clearly, slowing of my reactions, or slowing of my breathing.

\_\_\_\_\_ When I take these medications it may not be safe for me to drive a car, operate machinery, or take care of other people. If I feel sedated, confused, or otherwise impaired by these medications, I should not do things that would put other people at risk for being injured.

\_\_\_\_\_ When I take these medications regularly, I will become physically dependent on them, meaning that my body will become accustomed to taking the medications every day, and I would experience withdrawal sickness if I stop them or cut back on them too quickly. Withdrawal symptoms feel like having the flu, and may include abdominal pain, nausea, vomiting, diarrhea, sweating, body aches, muscle cramps, runny nose, yawning, anxiety, and sleep problems.

\_\_\_\_\_ I may become addicted to these medications and require addiction treatment if I cannot control how I am using them, or if I continue to use them even though I am having bad or dangerous things happen because of the medications.

\_\_\_\_\_ Anyone can develop an addiction to opioid pain medications, but people who have had problems with mental illness or with controlling drug or alcohol use in the past are at higher risk. I have told my provider if I or anyone in my family has had any of these types of problems.

\_\_\_\_\_ Taking too much of my pain medication, or mixing my pain medications with drugs, psychiatric medicine, or other medications that cause sleepiness, such as benzodiazepines, barbiturates, and other sleep aids, could cause me to be dangerously sedated or to overdose and stop breathing.

\_\_\_\_\_ I understand that taking certain medications such as buprenorphine (Suboxone®), Subutex®, naltrexone (ReVia®), nalbuphine (Nubain®), pentazocine (Talwin®), or butorphanol (Stadol®) will reverse the effects of my pain medicines and cause me to go into withdrawal.

\_\_\_\_\_ It is my responsibility to tell any provider that is treating me or prescribing me medications that I am taking opioid pain medications so that they can treat me safely and do not give me any medicines that may interact dangerously with my pain medicines.

\*Adapted from the American Academy of Pain Medicine  
<http://www.painmed.org/Workarea/DownloadAsset.aspx?id=321>

\_\_\_\_\_ I have discussed the possible risks and benefits of taking opioid medications for my condition with my provider and have discussed the possibility of other treatments that do not use opioid medications, including:

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\_\_\_\_\_These medications are being prescribed to me because other treatments have not controlled my pain well enough.

\_\_\_\_\_These medications are to be used to decrease my pain but they will not take away my pain completely.

\_\_\_\_\_These medications are to be used to help improve my ability to work, take care of myself and my family, and meet other goals that I have discussed with my provider, but if these medications do not help me meet those goals, they will be stopped.

\_\_\_\_\_ **For Men:** Taking opioid pain medications chronically may cause low testosterone levels and affect sexual function.

\_\_\_\_\_ **For Women:** It is my responsibility to tell my provider immediately if I think I am pregnant or if I am thinking about getting pregnant. If I become pregnant while taking these medications and continue to take the medicines during the pregnancy, the baby will be physically dependent on opioids at the time of birth and may require withdrawal treatment.

I have reviewed this form with my provider and have had the chance to ask any questions. I understand each of the statements written here and by signing give my consent for treatment of my pain condition with opioid medications.

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Patient signature

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Patient name printed

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Date

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Provider signature

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Provider name printed

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Date

\*Adapted from the American Academy of Pain  
Medicine

[http://www.painmed.org/Workarea/DownloadAsset.aspx?  
id=321\\_1](http://www.painmed.org/Workarea/DownloadAsset.aspx?id=321_1)

### **DRAFT MOTION #3**

The subcommittee believes that thorough understanding by patients of the risks of prescribed opioids and the alternatives to opioids is critical. Therefore, the subcommittee recommends that informed consent forms be required of all patients before any opioid drugs are prescribed, and that in addition to the existing requirements for such forms in the state regulations, that the state mandate that the forms require separate, affirmative acknowledgement by the patient of each of the following:

- a. The condition for which the opioids are being prescribed
- b. Reactions and side effects that can immediately result from opioid use
- c. Activities that may be dangerous when taking opioids
- d. The possibility of physical dependence on opioids and the manner in which that physical dependence can manifest itself.
- e. The possibility of addiction to opioids and the manner in which addiction to opioids can manifest itself.
- f. The increased risk of addiction associated with mental illness or past controlling drug or alcohol use.
- g. The risks associated with taking opioids at the same time as other prescription medications, specifically including but not limited to benzodiazapenes, barbituates, and other sleep aids.
- h. The possibility that taking specific types of medications can reverse the effects of opioids and cause a patient to go into withdrawal.
- i. The patient's responsibility to notify other health care providers of the patient's use of opioids.

The subcommittee approved Draft Motion #3 with modifications that will be circulated to committee members for review. The subcommittee voted unanimously.

5:48 p.m. – The question was raised as to how this will be presented legislatively – 1 bill or separate bills? Dr. Rattay added the informed consent form will be tweaked to best fit Delaware.

The three motions as modified are attached to these minutes as a draft document.

### **VI. Close Meeting**

5:55 p.m. – Meeting opened for public comment.

6:02 p.m. – Meeting adjourned.



***REPORT TO ADDICTION ACTION COMMITTEE***

**Mandated Insurance/Medicaid Coverage**

Having reviewed cost estimates prepared by Highmark, the State Employee Benefits Program, and the state's Medicaid program, the subcommittee recommends that the Addiction Action Committee issue a formal recommendation that the state make statutory changes to remove any insurance barriers to prescribers recommending and prescribing scientifically tested non-opioid treatments to their patients suffering from chronic back pain. Due to both cost and legal concerns, and given the absence of any other state models to review in order to predict the outcomes of this program with certainty, the subcommittee recommends that this step be taken in stages.

Specifically, the subcommittee recommends that state law be amended so that insurance plans with respect to which the state can mandate coverage be required to provide the following treatments to patients suffering from chronic back pain, in place of opioid drugs:

1. Physical therapy and exercise therapy, with no annual cap on the number of permitted visits. Coverage would not be required for maintenance treatment.
2. Chiropractic therapy, with no annual cap on the number of permitted visits. Coverage would not be required for maintenance treatment.
3. Psychological therapy (which should already be covered under the state's mental health insurance parity statute).

In subsequent years, the subcommittee recommends that state law be amended so that insurance plans with respect to which the state can mandate coverage be required to provide the following treatments to patients suffering from chronic back pain, in place of opioid drugs:

1. Massage therapy performed by a Delaware Licensed Massage Therapist.
2. Yoga instruction provided by an adequate network of providers meeting the insurer's quality standards.
3. Acupuncture by a Delaware licensed acupuncture therapist or Delaware licensed acupuncture and eastern medicine practitioner.

***DRAFT FOR APPROVAL BY SUBCOMMITTEE***

We also recommend that the state's Medicaid program afford the same coverage options to individuals on Medicaid with chronic back pain.

We also recommend that the State Employee Benefit Committee afford this coverage to individuals receiving their health insurance through the state's State Employee Benefit program.

Finally, we recommend that in the upcoming fiscal year, the state use one-time funds to initiate a pilot program allowing coverage for a targeted group of (in priority order) acupuncture, yoga, and massage therapy, so that the state can gather better state-specific evidence of both the cost and efficacy of those non-opioid pain treatments.

**Prescriber Education**

The subcommittee believes that proper education of prescribers with respect to the risks of opioid drugs and the effective alternatives to opioid drugs is critical. Therefore, the subcommittee recommends that the state's education requirements for persons holding licenses to dispense controlled substances in Delaware be amended to require that specific items be covered in the curriculum of approved courses, including the risks of opioid drugs, the importance of managing patients' cessation of opioid drugs when prescribed, and enumerated effective alternatives to opioid drugs. The subcommittee also recommends that the state complete its efforts to develop a state-authored continuing education course that would cover the aforementioned topics.

**Informed Consent**

The subcommittee believes that thorough understanding by patients of the risks of prescribed opioids and the alternatives to opioids is critical. Therefore, the subcommittee recommends that informed consent forms be required of all patients before any opioid drugs are prescribed, and that in addition to the existing requirements for such forms in the state regulations, that the state mandate that the forms require separate, affirmative acknowledgement by the patient of each of the following:

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- d. The possibility of physical dependence on opioids and the manner in which that physical dependence can manifest itself.
- e. The possibility of addiction to opioids and the manner in which addiction to opioids can manifest itself.
- f. The increased risk of addiction associated with mental illness or past controlling drug or alcohol use.
- g. The risks associated with taking opioids at the same time as other prescription medications, specifically including but not limited to benzodiazapenes, barbituates, and other sleep aids.
- h. The possibility that taking specific types of medications can reverse the effects of opioids and cause a patient to go into withdrawal.
- i. The patient's responsibility to notify other health care providers of the patient's use of opioids.
- j. The availability of non-opioid treatment options for some types of pain.